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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 09/447,490 | 11/23/1999 | RUDOLF ECKARDT | 105492-478-CON | 3882 |
| 24964 | 7590 | 02/17/2005 | EXAMINER | |
| GOODWIN PROCTER L.L.P 103 EISENHOWER PARKWAY ROSELAND, NJ 07068 | | | MCKENZIE, THOMAS C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/447,490 | ECKARDT ET AL. | |
| | Examiner | Art Unit | |
| | Thomas McKenzie, Ph.D. | 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004 and 02 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to an RCE and amendments filed on 5/7/04 as well as the New Power of Attorney and Change of Correspondence Address filed on 12/2/04. There are five claims pending and five under consideration. Claims 9-13 are method of making claims. This is the third action on the merits. The application concerns a process of making the anti-convulsant drug Carbamazapine from iminostilbene. Carbamazapine itself was first patented in 1960.

2. The history of the present claim 9 is murky. It was not present in the preliminary amendment of 11/23/99, in the amendment of 2/7/00, in the after final amendment of 3/20/00, in the after final amendment of 6/1/00, in the after final amendment of 6/5/00, or in the Appeal Brief of 7/25/00. The first appearance of claim 9 was in the Appeal Brief of 10/2/00. The Examiner's Answer of 12/1/00 concerned only claims 2-8 but stated in section (3) Status of Claims stated that Appellants' statement of the status of claims was correct. This statement was an error on the Examiner's part. The Appeal Brief of 10/2/00 stated that claim 9 was the previous claim 6 written in independent form and that claim 6 had been indicated as allowable. In fact, claim 6 had been rejected in the Final Rejection of 3/1/00 under 35 U.S.C. 112, first paragraph as containing new matter. On page 10 of the Decision on Appeal 2001-2585, the Board of Patent Appeals and Interferences noted that claim 9 was not pending in the application.

Priority

3. It is noted that this application appears to claim subject matter disclosed in prior Application No. 08/275,025, filed 7/14/94. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application.

See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Specification

4. The amendment filed 2/7/00 remains objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the

added phrase "or aqueous and alcoholic" in line 13, page 3 introduces a fourth and new solvent mixture. This issue is developed more thoroughly below in points #5-#8 and #10. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 2 of both claim 9 and claim 13, Applicants have the limitation that the reaction is to be conducted "in an aqueous solution". In lines 3 and 4 of both claim 9 and claim 13, Applicants list four solvents ("acidic medium") of which this aqueous solution consists. These four are acetic acid alone, acetic acid mixed with water, acetic acid mixed with alcohol, or "an aqueous alcohol". Acetic acid alone and acetic acid mixed with alcohol are not "an aqueous solution", since they contain no water. Yet the presence of some water in the reaction is mandatory because of the "aqueous solution" limitation no matter if that aqueous solution is a solvent for the reaction or merely a solvent used to introduce the alkali cyanate.

6. Claims 9, 10, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 3 of both claim 9 and claim 13, Applicants have the limitation that the reaction is to be conducted "in an acidic medium". In line 4 of both claim 9 and claim 13, Applicants list "aqueous alcohol" as one possible medium. Aqueous alcohol is not acidic since it does not contain any acid.

7. Claims 9, 10, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In lines 3 and 4 of both claim 9 and claim 13, Applicants list four solvents ("acidic medium") in which the claimed reaction is conducted. These include acetic acid mixed with alcohol, or "an aqueous alcohol". The singular use of "alcohol" in the third choice of solvents means that the art-recognized ethyl alcohol or ethanol is intended. However, what does "an aqueous alcohol" imply? Is this limited to a mixture of water and ethyl alcohol only? Does this cover water mixed with other alcohols like methyl or isopropyl? How about the alcohol 1-hexanol which will dissolve about 7% by weight of water?

8. In the alternative, Claims 9, 10, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 4 of both claim 9 and claim 13, Applicants list "aqueous alcohol" as one possible medium. If Applicants intend this to mean a three-part mixture of acetic acid, water and an alcohol, then the limitation is indefinite because it is unclear if a two-part or a three-part mixture is intended for reasons discussed above in point #5-#7.

9. Claims 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 2 of both claim 9 and claim 13, Applicants have the limitation "reacting iminostilbene with an alkali cyanate in an aqueous solution". Does this mean both the iminostilbene and the alkali cyanate are dissolved in water and the reaction proceeds in this medium? Or does it mean that a water solution of an alkali cyanate is added to the iminostilbene?

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter,

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The present claim 9 differs from claim 1 in parent application 08/275,025 by the insertion of the phrase "an aqueous solution said reacting being carried out in an acidic medium consisting of" after the phrase "cyanate in" in line 2, replacing the phrase "aqueous acetic acid" by the phrase "acetic acid with water", and replacing the phrase "within alcohol" by the phrase "or with alcohol, or with aqueous alcohol". The net result is that there are now four rather than the original three possible solvents. These four are acetic acid alone, acetic acid mixed with water, acetic acid mixed with alcohol, or "an aqueous alcohol". There is no mention in the specification of the use of "aqueous alcohol" as a concept although the individual components, water and the alcohol ethanol, are mentioned.

11. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In addition to the problem of the fourth solvent "aqueous alcohol", the claim is drawn to a two-part

process where iminostilbene is mixed with alkali cyanate in the absence of an acid, and then the iminostilbene-cyanate mixture is added to the "acidic medium". Nowhere in the specification is such a two-step process found.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Acklin (EP 277,095). The reference teaches a process of making the compound Carbamazapine from iminostilbene in acetic acid using sodium cyanate. The Applicant claims such a process comprising an aqueous solution of the cyanate. The reference teaches a process with 96% sulfuric acid present. The other 4% of the sulfuric acid is water. The process is shown in the reference in Example 2 in the third paragraph, page 10 of the translation of Acklin. The difference between the claims and the reference is Applicants' added limitation that the reaction is done in an aqueous solution and the presence of sulfuric acid in the reference example, not allowed by the present claims. The reference is silent as to whether the iminostilbene and/or alkali cyanate were in solution.

Claim 14 of reference as corrected by John Koytcheff on page 6 teaches, "that acetic acid is used as acidic agent, and concurrently as solvent". Thus, the reference teaches that acetic acid alone can function as the reaction medium. In lines 1-2, page 5, the reference teaches that "a mostly water- ... free organic solution" may be used for the reaction. The word "mostly" implies that small amounts of water are permitted by the reference.

The skilled organic chemist would be motivated to delete the sulfuric acid from the working example to reduce the costs of the reagents and to eliminate a disposal problem of the used sulfuric acid. The skilled organic chemist would understand that the working example contained 4% water and would vary the amount of water present as a part of routine experimentation to maximize the yields of this process, *Ex parte Rasmussen* 123 USPQ 498, *In re Aller* 105 USPQ 233.


13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Acklin (EP 277,095) as applied to claim 9 above. The two-step process of claim 13 has been characterized above in point 11. The reference teaches a one-step process. Just as a combination of two separately obvious process steps is unpatentable in the absence of unobvious results, Applicants' division of a one-step

process into two-steps is also obvious, *In re Fortess and Schoeneberg* 152 USPQ 13.

Conclusion

14. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

15. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571) 273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 9:00am to 5:30pm, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, acting SPE of Art Unit 1624, at (571)-272-0661.


Thomas C. McKenzie, Ph.D.
Primary Examiner
Art Unit 1624